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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,398	03/12/2004	Eric Donsky	38055.00005.UTL1	7171

23562 7590 01/03/2006

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PATENT DEPARTMENT
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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/800,398

Applicant(s)

DONSKY

Examiner

LaToya C. Younger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 5-12, 14-18, 26-28 and 33-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 13, 19-25 and 29-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-4, 13, 19-25, 29-32 in the reply filed on October 3, 2005 is acknowledged. All other pending claims (5-12, 14-18, 26-28, 33-61) are withdrawn as being directed to non-elected subject matter.

Drawings

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings on file are not formal and appear to be photographs of Applicants' device. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Observations

- In claim 19, the term "form" appears at line 3 of the claim. It is believed that Applicant intended the term "from". The same applies to claim 25, line 3.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-3, 13, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent

Application Publication 2003/0003458 (US Patent 6,855,538) to Pinkel et al.

Pinkel et al teach a microarray printing device. The device comprises a fluid receiving substrate (microarray substrate), as shown in figure 3, wherein the printing device spots fluid onto the microarray substrate. The printing device of Pinkel et al (shown in figure 1A) is designed to collect a volume of fluid (microliters in volume) and dispense the volume of fluid onto the microarray substrate. The printing device comprises a receiving device which is a support (14) designed to receive and hold a capillary tube collection device. The printing device also comprises a translation system, which is a guide rail (42) coupled with an actuator (48) for positioning the capillary tubes in relation to the microarray substrate. See col. 10, lines 18-24. With respect to claim 13, the capillary tube's vertical position is adjusted a spring mechanism (18). The printing device further comprises an expulsion device, which is a source of positive or negative pressure for sample loading and dispensing, as recited in claim 24.

It is noted that Pinkel et al does not disclose "osmolarity measuring". However, such has been taken as Applicant's intended use of the device, which has no relevance on the structure of the device. The device of Pinkel et al contains the same structural components as those present in Applicants' claimed device. Thus, the claims are anticipated.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 4, 19-23, 25, 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al.

The disclosure of Pinkel et al is described above. Pinkel et al differ from the instant invention in that tear film is not disclosed as the particular sample fluid as recited in claim 4.

With respect to tear film being the particular sample fluid used in the device, Pinkel et al teach using the device to collect and dispense small volumes of fluid from human organisms or tissues. While tear film is not specifically taught, one of ordinary skill in the art would have recognized that the device would be suitable for use with any small volume of fluid including tear film. Further, since the claims are directed to an apparatus, the material worked upon does not limit the apparatus itself. See MPEP 2115.

8. Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al in view of US patent 6,090,251 to Sundberg et al.

The disclosure of Pinkel et al is described above. Pinkel et al differ from the instant invention in that there is no disclosure of the particular expulsion devices recited in claims 29-32.

Sundberg et al teaches delivery of a small volume of sample fluid to a microsubstrate (32) using a printing system similar to that taught by Pinkel et al comprising a support (48) having capillary pins (38)

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for receiving a fluid sample. Sundberg et al teach that the fluid sample may be dispensed into a capillary channels (microchannels) on a microsubstrate. Sundberg et al teaches that sample fluid may be dispensed into the microchannels by wicking or by using a combination of electrophoretically and electroosmotically modifying the microchannels to change their hydrophilicity. See col. 9, lines 27-50.

It would have been obvious to one of ordinary skill in the art to dispel a fluid sample by allowing the sample to wick to a electrophoretically or electroosmotically-modified microchannel, as an alternative to the negative and positive pressure system taught by Pinkel et al. Sundberg et al teaches that the microchannel system would allow small volumes of fluid to move throughout a microsubstrate in an efficient manner.

9. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al in view of US patent 4,134,730 to Quame.

The disclosure of Pinkel et al is described above. Pinkel et al differ from the instant invention in that there is no disclosure of the particular expulsion devices recited in claim 22.

Quame teaches a spotting system for dispensing small volumes of liquid onto a substrate. The expulsion device of Quame comprises a bulb in conjunction with the capillary tube containing the fluid sample. The bulb is compressed allowing the fluid to be spotted onto a substrate. See abstract.

It would have been obvious to one of ordinary skill in the art to use a bulb mechanism, as an alternative to the negative and positive pressure system of Pinkel et al, as a means for dispensing sample fluid. Quame teaches that the mechanism is highly accurate and requires less cost than conventional methods (col. 1, lines 42-45).

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10. Claims 19-22, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al in view of US patent 6,955,881 to Tanaami.

The disclosure of Pinkel et al is described above. Pinkel et al differ from the instant invention in that the microarray substrate is not disclosed as having an associated electric field, as recited in claims 19-22, 25.

Tanaami teaches a method for dispensing DNA material onto a substrate. Tanaami uses a pin (capillary) having a small drop of DNA thereon to be spotted onto a substrate (42). Tanaami teaches applying an electric field to the substrate (42) to extend the sample across the substrate. Tanaami further teaches a control means for controlling the electrical charge from the electrodes (43, 44). See col. 3, lines 46-57, col. 4, lines 8-13).

It would have been obvious to one of ordinary skill in the art to incorporate electrodes on the microarray of Pinkel as a means to aid in depositing the sample onto the substrate. It is noted that Applicants use the electric field for a different reason than Tanaami. However, rationale different from Applicants is permissible (MPEP 2144). With respect to the limitations regarding the manner in which the device operates to use the electric field (claims 19-22, 25), it should be noted that the claims are directed to an apparatus, which is limited by its structure and not the manner in which it functions.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya C. Younger whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Thursday 10:30 a.m. - 7:00 p.m. and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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